# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

# Meeting of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC)

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland June 28-29, 2016

#### DRAFT MEETING ROSTER

## **DESIGNATED FEDERAL OFFICER (Non-Voting)**

# Lauren D. Tesh, PharmD, BCPS

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

# ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

## Deborah K. Armstrong, MD

Professor of Oncology

The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

The Johns Hopkins University School of Medicine

Baltimore, Maryland

# Alberto S. Pappo, MD

(Chairperson, pedsODAC)

Member and Head, Division of Solid Malignancies

St Jude Children's Research Hospital

**Professor of Pediatrics** 

University of Tennessee Health Science Center

Memphis, Tennessee

## ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

# Phuong Khanh (P.K.) Morrow, MD, FACP

(Industry Representative)

Executive Medical Director, Amgen Oncology

Therapeutic Area Head, US Medical Organization

Thousand Oaks, California

# **TEMPORARY MEMBERS (Voting)**

# Peter C. Adamson, MD

(Day 1 Only)

Chair, Children's Oncology Group

Alan R. Cohen Endowed Chair in Pediatrics The Children's Hospital of Philadelphia

Philadelphia, Pennsylvania

# Steven G. DuBois, MD, MS

Director, Experimental Therapeutics Dana-Farber/Boston Children's Hospital

Faculty of Pediatrics, Harvard Medical School

Boston, Massachusetts

## Patrick Brown, MD

Director, Pediatric Leukemia Program

Associate Professor of Oncology and Pediatrics Sidney Kimmel Comprehensive Cancer Center Johns Hopkins University School of Medicine

Baltimore, Maryland

# Ira J. Dunkel, MD

Member

Memorial Sloan-Kettering Cancer Center

**Professor of Pediatrics** 

Weill Cornell Medical College Department of

**Pediatrics** 

New York, New York

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# **DRAFT MEETING ROSTER (cont.)**

#### TEMPORARY MEMBERS (Voting) (cont.)

#### Julia Glade Bender, MD

Associate Professor of Pediatrics at Columbia University Medical Center Associate Director, Division of Pediatric Hematology, Oncology and Stem Cell Transplantation Medical Director, Developmental Therapeutics and Precision Medicine Programs New York, New York

## Tobey J. MacDonald, MD

Aflac Chair for Pediatric Neuro-Oncology Professor of Pediatrics Emory University School of Medicine Director, Pediatric Neuro-Oncology Program Aflac Cancer & Blood Disorders Center Children's Healthcare of Atlanta Atlanta, Georgia

# Kathleen A. Neville, MD, MS

Director, Experimental Therapeutics Program
Professor of Pediatrics, University of Arkansas for
Medical Sciences
Section of Clinical Pharmacology and Toxicology
Arkansas Children's Hospital
Little Rock, Arkansas

#### Nita L. Seibel, MD

Head, Pediatric Solid Tumor Therapeutics Clinical Investigations Branch, CTEP/Division of Cancer Treatment and Diagnosis National Cancer Institute, NIH Adjunct Professor of Pediatrics George Washington University School of Medicine and Health Sciences Bethesda, Maryland

#### Brenda Weigel, MD, MSc

Associate Professor Developmental Therapeutics Chair Children's Oncology Group Division Director, Pediatric Hematology/Oncology University of Minnesota Minneapolis, Minnesota

#### Pamela Haylock

(Acting Consumer Representative)
Medina, Texas

## Gigi McMillan

(Patient Representative) Manhattan Beach, California

## Elizabeth A. Raetz, MD

Professor of Pediatrics Pediatric Hematology/Oncology University of Utah Huntsman Cancer Institute Primary Children's Hospital Salt Lake City, Utah

#### Katherine E. Warren, MD

Head, Pediatric Neuro-Oncology Pediatric Oncology Branch National Cancer Institute, NIH Bethesda, Maryland

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# **DRAFT MEETING ROSTER (cont.)**

# FDA PARTICIPANTS (Non-Voting)

### Richard Pazdur, MD

Director

Office of Hematology Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA

## Edvardas Kaminskas, MD

(Morning Session, Day 2 Only)
Deputy Director
Division of Hematology Products (DHP)
OHOP, OND, CDER, FDA

#### Amy Barone, MD

(Morning Session, Day 1) (Afternoon Session, Day 2) Medical Officer DOP II, OHOP, OND, CDER, FDA

## Rachel Ershler, MD

(Morning Session, Day 2 Only) Medical Officer DHP, OHOP, OND, CDER, FDA

## **Christy Osgood, MD**

(Morning Session, Day 2 Only) Medical Officer DOP II, OHOP, OND, CDER, FDA

## Joohee Sul, MD

(Afternoon Session, Day 2 Only) Medical Officer DOP II, OHOP, OND, CDER, FDA

### Gregory Reaman, MD

Associate Director for Oncology Sciences OHOP, OND, CDER, FDA

## Martha Donoghue, MD

(Afternoon Session, Day 1 Only)
Acting Associate Director
Division of Oncology Products (DOP) II
OHOP, OND, CDER, FDA

#### Lori Ehrlich, MD, PhD

(Morning Session, Day 10nly) Medical Officer DHP, OHOP, OND, CDER, FDA

# Robert (Skip) Nelson, MD

(Afternoon Session, Day 2 Only)
Deputy Director and Senior Pediatric Ethicist
Office of Pediatric Therapeutics
Office of the Commissioner, FDA

## Jeffrey D. Seidman, MD

(Afternoon Session, Day 2 Only)
Medical Officer/Pathologist
Molecular Pathology and Cytology Branch
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics and Radiological
Health
Center for Devices and Radiological Health, FDA